

REMARKS

I Disposition of Claims

Claim 13-26 are currently pending. Claim 13 has been amended to differentiate the claimed method from protection from background terrestrial radiation. Support for the amended claim can be found throughout the specification, for example in the original claims and Example 3, particularly page 35, line 18-page 36, line 1. Claims 14-17 have been amended to clarify antecedent basis, and thus for reasons unrelated to patentability. New Claims 20-26 are supported throughout the specification, for example in the original claims and on page 21, third full paragraph. No new matter has been added.

II Claim Objection

The Examiner has objected to Claim 13 because of the misspelling of the term “at least”. The spelling has been corrected.

III Compliance with 35 USC 112, first paragraph

The Examiner has rejected Claims 12-19 under 35 USC 112, first paragraph as failing to comply with the written description requirement. The Examiner feels that there is not support in the specification for the step of “determining that a subject will be exposed to said x-rays, gamma rays and/or electron beams”.

According to MPEP 2163: “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.”

The Examiner is directed to the Background section of the Specification, page 17, line 23-25, and page 18, lines 8-12, wherein the applicant identifies several subjects that would be exposed to radiation and in need of protection, for example miners, flight crews, astronauts, military personnel, radiological technologists and radiation facility workers. The Specification also identifies environments in which a subject would be exposed and need protection (radiation facilities, p18, line 12; mines, p 1, line 22). One of skill in the art would clearly understand from this description that the inventor was in possession of the first step of “determining that a subject will be exposed”. Therefore, the written description requirement has been satisfied and the rejection should be withdrawn.

IV Compliance with 35 USC 112, second paragraph

The Examiner has rejected claims 14-17 under 35 USC 112, second paragraph as being indefinite. The Examiner indicated that the dependent claims referred to “a subject” rather than “the subject” of the independent claim. The Claims have been amended to refer to “the subject” of the independent claim.

V. Novelty and Non-Obviousness

The Examiner has rejected Claims 13-19 under 35 USC 102(b) as being anticipated by “Official Notice of commercially available materials comprising collagen, keratin, or silk”. The Examiner further rejected Claim 13-19 under 35 USC 102(b) as being anticipated by Pauly et al. (US 2003/0091518-A1). The Examiner has further rejected Claims 13-19 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Urita (JP 10-338615-A). The Examiner has rejected Claims 13-19 under 35 USC 102 (b) as anticipated by, or in the alternative, under 35 USC 103(a) as obvious over Natsume et al. (JP 01-280465-A), Erwin (US 4946450), Sano (US 5718954-A), Sakaki (US 5587411-A), and Sato (US 4638024), individually.

Pending claims 13-19 relate to a method for preventing or reducing the adverse effects of exposure to 10 kGy or more of radiation of at least one member selected from the group consisting of X-rays, gamma rays, and electron beams on a subject that has been determined to be exposed to such radiation by using collagens, keratins, and/or silk fibroins. Further, newly pending claims 20-26 are specifically drawn to a method of preventing or reducing the adverse effects of exposure to electron beams on a subject that has been determined to be exposed to such radiation by using collagens, keratins, and/or fibroins.

The Examiner has asserted that without the recitation of “any limitations on levels of radiation exposure...it is noted that such radiation is present all the time, particularly gamma rays and x-rays are present from terrestrial and cosmic sources as a background all the time.” Claims 13-19 have been amended to include the limitation “exposed to 10 kGy or more” so as to differentiate from exposure to background radiation of gamma rays and x-rays.

Pauly et al. (US2003/0091518) discloses cosmetics and/or pharmaceutical preparations comprising a *Brassicaceae* extract together with UV/IR-light protection agents. Example 11 (Table 7). etc., of Pauly disclose formulae of cosmetics comprising keratin and/or collagen.

However, Pauly does not disclose that collagens, keratins, and silk fibroins act as protection agents against X-rays, gamma rays, and electron beams at levels of 10 kGy or more.

Urita et al. (JP10-338615) merely discloses that natural silk fibroins can absorb infrared rays, and that protection from harmful sunrays is possible by using cosmetics containing natural silk fibroins. Urita nowhere suggests that natural silk fibroins have protective effects against x-rays, gamma rays, and electron beams at levels of 10 kGy or more.

Natsume et al. (JP01-280465) merely discloses that collagens can be formed into a film. Natsume nowhere teaches or suggests that collagens have protective effects against X-rays, gamma rays, and electron beams at levels of 10 kGy or more.

Erwin (US4946450) discloses that collagens can be used as an eye shield. However, Erwin nowhere suggests that collagens can act as protection agent against X-rays, gamma rays, and electron beams.

Sano et al. (U55713954) discloses that materials containing fine particles of natural organic material, and that such fine particles can provide the materials with humidity absorption/releasing properties, humidity permeability, compressibility. etc. However, Sano merely discloses silk powder and others as examples of fine particles of natural organic materials. Sano nowhere suggests protection effects against X-rays, gamma rays, and electron beams at levels of 10 kGy or more.

Sakaki et al. (1355587411) merely discloses a composition comprising keratins or other proteins as a rubber composition having enough strength for practical use and is harmless to human beings. Sakai nowhere teaches or suggests that keratins have protection effects against X-rays, gamma rays, and electron beams at levels of 10 kGy or more.

Sato et al. (US4638024) merely discloses a composition containing protein such as glue (keratins is a main constituent of protein-based glue) as a polymer composition for use in microcapsule, photosensitive material, etc. Sato is silent about protection effects against X-rays, gamma rays, and electron beams at levels of 10 kGy or more.

By the “Official Notice of commercially available materials comprising collagen, keratin or silk” the Examiner does not provide evidence that it was known to those of skill in the art that these materials had protection effects against X-rays, gamma rays, and electron beams at levels of 10 kGy or more.

As described above, none of the cited references, teach or suggest anything that even suggests that collagens, keratins, and silk fibroins have protective effects against x-rays, gamma rays, electron beams. Therefore, nothing in the cited references, either alone or in combination, would suggest the recited step of determining that a subject will be exposed to X-rays, gamma rays, or electron beams. As a result, none of these references could possibly disclose or suggest the step recited in the claims of protecting the subject with collagen, keratin, silk fibroins or their derivatives in response to the determination.

Further, terrestrial background levels of these forms of radiation are below the level of exposure the method teaches protection from, so a subject would not be practicing this claim by "existing on Earth" as the Examiner asserts. Accordingly, it is not obvious to one of ordinary skill in the art to first determine whether a subject will be exposed to the recited forms and amount of radiation and then based on that determination, blocking or reducing the adverse effects of the radiation by using collagens, keratins, and/or silk fibroins or their derivatives. Accordingly, claims 13 to 19 are neither anticipated by nor rendered obvious over the cited references and the official notice.

CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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Dated: 6-29-2006

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